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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,864	04/30/2007	Peter Skufca	8054-006-US	9882

32301 7590 01/28/2010

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EXAMINER	
LI, RUIXIANG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
01/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,864	SKUFCA ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/2006, 09/05/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Applicants' preliminary amendment filed on 04/20/2006 has been entered in full. Claims 1-32 are pending and are currently under consideration.

Information Disclosure Statement

2. The information disclosure statements filed on 12/22/2006 and 09/05/2006 have been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

Drawings

3. The drawings filed on 04/20/2006 are accepted by the Examiner.

Claim Rejections—35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-25, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-25, 31, and 32 provide for the use of succinate in the form of a free acid or in the form of a salt thereof for stabilizing G-CSF in a composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 23-25, 31, and 32 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

6. Claims 8-10 recite the limitation "wherein the surfactant…", “wheein the complexing agent…", and “wherein the isotonizing agent…" respectively. There is insufficient antecedent basis for the limitations in claim 7, from which they depend from.

Claim Rejections—35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an

application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-27, and 30-32 are rejected under 35 U.S.C. 102 (b) as being anticipated by Liu et al. (US 2002/0045571 A1, Apr. 18, 2002).

Liu et al. teach a stable liquid formulation comprising a protein in an amount of at least about 80mg/ml and a salt and/or buffer in an amount of at least about 50 mM (claim 1), having a pH of 4.0 to 5.3 (paragraph [0012]), and a method of preparing such a composition (see, e.g., paragraph [0010]; paragraph [0055]).

Liu et al. also teach a stable liquid formulation comprising a protein in an amount of at least about 80mg/ml and a pharmaceutically acceptable acid, base, and/or buffer in an amount of at least about 50 mM so as to have either a pH of about 4.2 to about 5.3 [claim 45]). A pharmaceutically acceptable acid includes citric acid, a portion of which would exist in a form of citrate in the formulation under the buffered condition.

Liu et al teach that various proteins can be formulated, such as G-CSF (page 4, left column, line 6). Liu et al. teach pharmaceutically acceptable buffers and salts include succinate (page 7, right column, paragraph [0060]). Liu et al. teach suitable bases include those formed from inorganic base forming metals include alkali metals, alkaline earth metal (claim 7), such as sodium (paragraph [0058]). It is noted that the succinic acid has a pKa1 4.21 and pKa2 5.64, and a succinate buffer has an effective pH range of 3.8 to 6.0.

Liu et al. teach the formulation comprises a surfactant (claim 19), such as polysorbate (paragraph [0012]), or a lyoprotectant (claims 15-16), such as mannitol or sorbitol (page 7, paragraph [0061]). Liu et al. teach that the formulation may be administered by infusion or injection (page 15, paragraphs [0148] and [0149]). Liu et al. teach that for intravenous administration, a lower concentration of the protein, for example, about 5-50 mg/ml in the reconstituted formulation may be desired (page 15, left column, lines 4-7).

Liu et al. teach a lyophilized formulation (see, e.g., paragraph [0054]) and a reconstituted formulation (paragraph [0055]). Since a lyophilized formulation optionally comprises a surfactant (claim 19), such as polysorbate (paragraph [0012]), the formulation prepared from the lyophilized formulation would comprise liposomes.

Accordingly, the teachings of Liu et al. meet the limitations of claims 1-27, and 30-32.

Claim Rejections under 35 USC § 103(a)

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (US 2002/0045571 A1, Apr. 18, 2002) as applied to claims 1-27 and 30-32 above, and further in view of Chmielewski et al. (US Patent No. 7,001,892 B1, Feb.

21, 2006; 102 (e) date: June 11, 1999).

Liu et al. teach a stable liquid formulation comprising G-CSF applied to claims 1-27 and 30-32 above,

Liu et al. do not teach the specific concentration of G-CSF in the formulation recited in claims 28 and 29.

Chmielewski et al. teach the formulation of G-CSF for human administration use comprising 0.25 mg/ml or 0.50 mg/ml (the middle of column 17-18).

Therefore, it would have been obvious to one of skilled in the art to modify the formulation of Liu et al. and to prepare a formulation comprising G-CSF at the concentration 0.25 mg/ml or 0.50 mg/ml as taught by Chmielewski et al. with a reasonable expectation of success. One would have been motivated to do so because for intravenous administration, a lower concentration is desired as taught by Liu et al. (page 15, left column, the first paragraph) and Chmielewski et al. teach the formulation of G-CSF for human administration use comprising 0.25 mg/ml or 0.50 mg/ml (the middle of column 17-18).

Claim Objections

12. Claim 16 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 16 is an improper multiple dependent claim whereas Claim 17 depends from Claim 16.

Conclusion

13. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
January 26, 2010